



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

APR 12 2004

Dr. Francisco Kasse Acta  
Jefe de Inspeccion Mataderos de Exportacion  
Direccion General Salud Ambiental  
Secretaria de Estado de Salud Publica y Asistencia Social  
Ave. San Cristóbal esq. Ave. Tiradentes  
Santo Domingo, Dominican Republic

Dear Dr. Kasse Acta:

The Food Safety and Inspection Service has completed an on-site audit of the Dominican Republic's meat inspection system. The audit was conducted from September 16 - 25, 2003. Comments from the Dominican Republic have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by facsimile at 202-690-4040, or by e-mail at [sally.stratmoen@fsis.usda.gov](mailto:sally.stratmoen@fsis.usda.gov).

Sincerely,

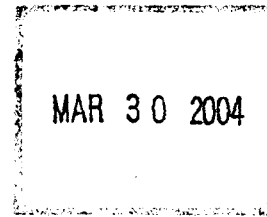
Sally Stratmoen  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

David Salmon, Attaché, US Embassy, Santo Domingo  
Judith Marcano, Commercial Counselor, Embassy of the Dominican Republic  
Linda Swacina, Deputy Administrator, FSIS  
Jeanne Bailey, FAS Area Officer  
Amy Winton, State Department  
Karen Stuck, Assistant Administrator, OIA, FSIS  
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Country File

**FINAL**



FINAL REPORT OF AN AUDIT CARRIED OUT IN THE DOMINICAN  
REPUBLIC COVERING THE DOMINICAN REPUBLIC'S MEAT  
INSPECTION SYSTEM

SEPTEMBER 16 THROUGH SEPTEMBER 25, 2003

Food Safety and Inspection Service  
United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Office of Public Health)
OPH	Office of Public Health
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

## 1. INTRODUCTION

The audit took place in the Dominican Republic from September 16 through September 25, 2003.

An opening meeting was held on September 16, 2003, in Santo Domingo with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Dominican Republic's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, Office of Public Health (OPH).

## 2. OBJECTIVE OF THE AUDIT

This audit was a special audit at the request of the Dominican Republic. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishment certified by the CCA as eligible to export meat products to the United States. A special emphasis was placed on government oversight and Hazard Analysis Critical Control Point (HACCP) and Sanitation Standard Operating Procedures (SSOP) implementation.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, located in Santo Domingo, Dominican Republic, one laboratory performing analytical testing on United States-destined product, and one beef slaughter and processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	0	
	Autonomous Province	0	
	Local	1	Establishment level
Laboratories		1	
Meat Slaughter and Processing Establishments		1	
Meat Processing Establishments		0	
Cold Storage Facilities		0	

## 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters. The third part involved an on-site visit to one slaughter and processing establishment. The fourth part involved a visit to one government laboratory. The Central Veterinary Laboratory was conducting analyses of field samples for the presence

of generic *Escherichia coli* (*E. coli*) and *Salmonella* and for the Dominican Republic's national residue control program.

Program effectiveness determinations of the Dominican Republic's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. The Dominican Republic's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by the Dominican Republic and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained that the Dominican Republic's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for the Dominican Republic. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for the Dominican Republic under provisions of the Sanitary/Phytosanitary Agreement. There are currently no equivalence determinations that have been made by FSIS for the Dominican Republic.

#### 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:  
[www.fsis.usda.gov/OPPDE/FAR/index.htm](http://www.fsis.usda.gov/OPPDE/FAR/index.htm).

The Dominican Republic voluntarily delisted all establishments in January 1999.

The last FSIS audit of the Dominican Republic's meat inspection system was conducted in August 1997.

The following problems were identified during the 1997 audit:

- Dripping condensation was observed in the carcass chiller.
- Edible and inedible containers were not identified in the slaughter and boning rooms.
- The coldest area of the oven used to cook salami was not identified.
- Door seals for outside doors were not sufficient.
- Flies were observed in the slaughter and boning rooms.
- Arsenic was not analyzed this year.
- Intra-Laboratory check samples were not performed for *Listeria* and species verification.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

Meat inspection activities are centrally organized at the Office of Public Health (OPH), located in Santo Domingo, Dominican Republic. Implementation of inspection activities is accomplished by the Veterinarian-in-Charge of the official establishment. Verification of implementation is accomplished by monthly supervisory reviews conducted by the Chief Meat Inspector. The OPH is responsible for legal and regulatory authority for the administration of the meat inspection program. The Dominican Republic is divided into nine regions. The Veterinarian-in-Charge or Inspector-in-Charge of domestic establishments reports directly to the regional office. The Veterinarian-in-Charge of the one export establishment reports directly to the Chief Meat Inspector. Export establishments are directly supervised by the OPH. The Environmental Health Director and the Food Control Director, working within the OPH, are active in government oversight of export establishments.

In the central headquarters in Santo Domingo, in order to gather more information on oversight, interviews were conducted with the officials responsible for:

- Field operations and inspection services
- SSOP and HACCP programs
- National residue program
- Microbiological sample program
- Live animal disease programs
- Export programs and U. S. regulations
- Monthly supervisory visits
- Enforcement and prosecution
- Training

In the local inspection offices interviews were conducted with the Veterinarian-in-Charge responsible for:



- Inspection services
- Enforcement and compliance
- Training

No concerns arose as a result of the interviews except as noted below:

- The Dominican Republic's meat inspection program does not have an official program in place to monitor for Bovine Spongiform Encephalopathy.

#### 6.1.1 CCA Control Systems

The Chief Meat Inspector, located at the OPH office in Santo Domingo, is in charge of export activities for all certified establishments. This official performs the required monthly supervisory reviews to verify establishment compliance with FSIS requirements. The official export establishment list is maintained and controlled at the central office, by the Chief Meat Inspector. New official inspection guidelines and regulations are issued by OPH in Santo Domingo. These are provided by fax, and/or hard copy to the inspection offices of the individual establishments. The Chief Meat Inspector is responsible for assuring FSIS requirements are implemented by the Veterinarian-in-Charge.

#### 6.1.2 Ultimate Control and Supervision

Control of inspection activities and supervision of non-veterinary inspectors in slaughter establishments, is the responsibility of the Veterinarian-in-Charge. The Veterinarians-in-Charge are directly supervised by the Chief Meat Inspector. The Chief Meat Inspector is responsible for program delivery and assuring export requirements are implemented in slaughter and processing establishments. There are no written guidelines for supervision of subordinates, evaluation of performance, pay increases or promotion of inspection personnel. Supervision, evaluation, pay increases and promotions are verbal and done at the discretion of the supervisor. Official inspectors may receive pay increases based on the number of years of service.

Although staffing appeared to be adequate in the individual establishment, problems were identified in enforcing FSIS requirements. The CCA did not have ultimate control over the supervision of government inspectors. Identified problems will be reported in Section 6.1.3 of this report.

#### 6.1.3 Assignment of Competent, Qualified Inspectors

OPH is responsible for hiring and payment of all employees and ensures adequate training of inspectors before assignment to an official establishment. New inspectors receive class room training and must pass a test to retain their position. On-the-job training is carried out by the Veterinarian-in-Charge in each establishment. New veterinarians receive class room training, but are not tested. The Chief Meat Inspector and the Veterinarian-in-Charge of the certified establishment received HACCP training at the 2002 International Seminar for Foreign Government Officials conducted in Puerto Rico. Continuous daily inspection was provided for the establishment certified to export

beef products to the United States. The following problems were identified in the assignment of competent, qualified inspectors:

- Control and supervision of inspectors was inadequate at the local level.
- FSIS requirements were not enforced.

No full-time or part-time government employee is permitted to perform any private, establishment paid tasks at an establishment in which they perform official duties. There are no provisions for private veterinarians to be hired under contract as part-time government employees. Government employed veterinarians are allowed to engage in private veterinary practice. Non-veterinarians are not hired as part-time employees.

#### 6.1.4 Authority and Responsibility to Enforce the Laws

The CCA has the authority and responsibility to enforce U.S. requirements. Each establishment has copies of the pertinent Dominican Republic and U.S. rules and regulations.

Export requirements for the establishment certified to export to the United States are verified by the Veterinarian-in-Charge, but documentation of inspection activities was not performed. The following activities were not documented:

- Operational sanitation activities and HACCP verification activities were not documented.

Problems identified in enforcement of FSIS requirements will be reported in Section 13 of this report.

There are written procedures for product recalls. Polyvalent (multi-commodity) inspectors aid in the identification of recall products and lead the investigative process. The Food Control Director and the Chief Meat Inspector will initiate and finalize the process. Local police will aid in the confiscation of recalled product. Press releases are used to notify the public. There are written procedures for initiating legal and punitive actions.

#### 6.1.5 Adequate Administrative and Technical Support

The government of the Dominican Republic has adequate administrative and technical support in the central office to operate and support its inspection system, including experts, specialists and adequate facilities.

### 6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the central headquarters office located in Santo Domingo. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.

- Supervisory visits to establishments that were certified to export to the United States.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as Tuberculosis, Brucellosis and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Control of rendering and feed manufacturing facilities.

No concerns arose as a result of the examination of these documents, except as reported in Section 10.

#### 6.3.1 Audit of Regional and Local Inspection Sites

The Dominican Republic is divided into nine regional offices, but they are not involved in government oversight of export establishments. Results of the audit of the inspection office located in the individual establishment will be reported in Section 13 of this report.

### 7. ESTABLISHMENT AUDITS

The FSIS auditor visited one slaughter/processing establishment.

Specific deficiencies are noted in the attached individual establishment audit forms.

### 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

The residue laboratory audit focused on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were reviewed:

The Central Veterinary Laboratory located in Santo Domingo is a government laboratory that performs residue and microbiological testing for product exported to the United States. Audit results for the residue section of the Central Veterinary Laboratory will be

reported under section 12 of this report. Deficiencies noted in the microbiology section of the Central Veterinary Laboratory are noted below:

- Inter-laboratory check sample programs were not in place at this laboratory.
- International check sample programs were not in place at this laboratory.

## 9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess the Dominican Republic's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, the Dominican Republic's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, the Dominican Republic's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

### 9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in the one establishment audited was found to meet the basic FSIS regulatory requirements, with no deficiencies.

The following deficiencies regarding SSOP ongoing requirements were noted:

- SSOP were not effectively implemented.
- Records documenting implementation, maintenance and effectiveness, and corrective actions of the SSOP were incomplete or missing.

### 9.2 Sanitation

The following sanitation deficiencies were noted (further details may be found in the individual Foreign Establishment Audit Checklists, which are attached to this report):

- Construction and maintenance controls were not effective.
- Condensation was identified in product areas.
- Sanitation controls for sanitary operations were not effective.

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that the Dominican Republic's inspection system had adequate controls in place except as noted below:

- Condemned product controls were not effective. Dead and condemned cattle were brought into the slaughter establishment after normal production hours to prepare the dead animals for on-site rendering.

Imported animal by-products used in the manufacturing of animal feeds are regulated and their use is restricted. There are no regulations governing the manufacturing, distribution and use of animal by-products rendered and used for animal feed within the Dominican Republic. The following observation was noted:

- Meat and bone meal rendered and prepared at this establishment's on-site rendering facility is fed to cattle owned by this establishment or sold to other livestock producers. The meat and bone meal offered for sale was not labeled.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

## 11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

### 11.1 Humane Handling and Slaughter

No deficiencies were noted.

### 11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audit of the one establishment. Basic HACCP requirements were met in the establishment audited. The establishment had not adequately implemented HACCP requirements. The following deficiencies regarding HACCP ongoing requirements were noted:

- Monitoring of the HACCP plan was not adequate.
- Verification and/or validation documentation was inadequate or missing.
- Corrective actions written in the HACCP plan were not adequate.
- The HACCP plan was not reassessed annually. The HACCP plan was not reassessed for *E. coli* O157:H7.
- Records documenting corrective actions were incomplete.

#### 11.3 Testing for Generic *E. coli*

The Dominican Republic has adopted the FSIS regulatory requirements for generic *E. coli* testing.

The establishment audited was required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was not conducted properly. The following deficiencies were identified:

- The establishment did not have a written procedure for testing for generic *E. coli*.
- The carcass selection method was not random.
- The sample collector was not using aseptic collection techniques.
- The sample collector was using a 50 square centimeter template in lieu of the required 100 square centimeter template.
- Statistical process control procedures had not been developed, as required, to evaluate the results of testing for generic *E. coli*.
- Results were not recorded on a process control chart.

#### 11.4 Testing for *Listeria monocytogenes*

The establishment audited was not producing ready-to-eat products for export to the United States and was not required to reassess their HACCP plan to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

### 12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The Central Veterinary Laboratory located in Santo Domingo, Dominican Republic is a government laboratory that performs residue testing for product exported to the United States. The following deficiencies were noted:

- Levamisole, Ivermectin, Benzimidazoles and arsenic were not analyzed this year.
- Inter-laboratory check sample programs were not in place at this laboratory.
- International check sample programs were not in place at this laboratory.

The Dominican Republic's National Residue Testing Plan for 2003 was being followed and was on schedule except as noted below:

- Arsenic was not analyzed this year.

### 13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

#### 13.1 Daily Inspection in Establishments

Direct and continuous official supervision was provided in the slaughter establishment audited.

#### 13.2 Testing for *Salmonella*

The Dominican Republic has adopted the FSIS regulatory requirements for testing for *Salmonella*.

The one establishment audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* species was not conducted in accordance with FSIS requirements. The following deficiencies were identified:

- The sample collector for the collection of *Salmonella* Performance Standards set samples was not using aseptic collection techniques.
- The carcass selection method for collection of *Salmonella* samples was not random.
- The sample collector for collection of *Salmonella* samples was using a 50 square centimeter template in lieu of the required 100 square centimeter template.
- The sample results for *Salmonella* samples were not recorded as sample sets.

#### 13.3 Species Verification

Species verification was not conducted in the establishment audited.

#### 13.4 Monthly Reviews

During this audit it was found that in the certified establishment visited, monthly supervisory reviews were being performed and documented as required.

#### 13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. Inspection controls were not effective in the establishment audited and deficiencies should have been identified by the on-site and supervisory Dominican Republic meat inspection officials before this audit. Inspection controls identified as not effective are noted:

- FSIS regulatory requirements were not enforced. SSOP and HACCP requirements as identified in the individual establishment reports were not identified by Dominican Republic meat inspection officials in SSOP and HACCP verification activities as non-compliances to be corrected by the establishment.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

#### 14. CLOSING MEETING

A closing meeting was held on September 25, 2003, in Santo Domingo, with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Don Carlson  
International Audit Staff Officer





## 15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Reports

Foreign Country Response to Draft Final Audit Report

09/18/03

Central Veterinary Laboratory (Residue)

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY  
Office of Public Health

CITY & COUNTRY  
Santo Domingo, Dominican  
Republic

ADDRESS OF LABORATORY  
Av. Monumental Los Girasoles

NAME OF REVIEWER  
Dr. Don Carlson

NAME OF FOREIGN OFFICIAL  
Dr. Eduardo Brea Tio

Residue Code/Name			100	200	300	400	500	800						
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01												
	Sampling Frequency	02	A	A	A	A	A	A						
	Timely Analyses	03	A	A	A	A	A	A						
	Compositing Procedure	04	O	O	O	O	O	O						
	Interpret Comp Data	05	O	O	O	O	O	O						
	Data Reporting	06	A	A	A	A	A	A						
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE											
	Correct Tissue(s)	08												
	Equipment Operation	09												
	Instrument Printouts	10												
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE											
	Recovery Frequency	12												
	Percent Recovery	13												
	Check Sample Frequency	14												
	All analyst w/Check Samples	15												
	Corrective Actions	16												
	International Check Samples	17												
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE						O	O	O	O	O	O
OTHER REVIEW		19	EVAL. CODE											
		20	EVAL. CODE											

SIGNATURE OF REVIEWER

DATE

09/18/03

## FOREIGN COUNTRY LABORATORY REVIEW

*(Comment Sheet)*

REVIEW DATE

09/18/03

NAME OF FOREIGN LABORATORY

Central Veterinary Laboratory (Residue)

FOREIGN GOV'T AGENCY

Office of Public Health

CITY &amp; COUNTRY

Santo Domingo, Dominican  
Republic

ADDRESS OF LABORATORY

Av. Monumental Los Girasoles

NAME OF REVIEWER

Dr. Don Carlson

NAME OF FOREIGN OFFICIAL

Dr. Eduardo Brea Tio

RESIDUE	ITEM NO.	COMMENTS
401		1. The Central Veterinary Residue Laboratory was not testing for Arsenic, Levamisole, Ivermectin and Benzimidazoles.
910		
923		
950		
		2. Inter-laboratory and international laboratory check sample programs had not been established.
		Comments: The Central Veterinary Residue Laboratory was conducting residue analysis on product for potential export to the United States and for Dominican Republic's domestic residue program. This laboratory was using approved AOAC methods but was not ISO 17025 accredited.

Central Veterinary Laboratory (Microbiology)

ADDRESS OF LABORATORY  
Av. Monumental Los Girasoles

NAME OF FOREIGN OFFICIAL  
Dr. Eduardo Brea Tio

SIGNATURE OF REVIEWER	DATE
<i>W. Son Carter</i>	09/18/03

# FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

09/18/03

NAME OF FOREIGN LABORATORY

Central Veterinary Laboratory (Microbiology)

FOREIGN GOV'T AGENCY

Office of Public Health

CITY & COUNTRY

Santo Domingo, Dominican Republic

ADDRESS OF LABORATORY

Av. Monumental Los Girasoles

NAME OF REVIEWER

Dr. Don Carlson

NAME OF FOREIGN OFFICIAL

Dr. Eduardo Brea Tio

RESIDUE

ITEM NO.

COMMENTS

Comments:

1. Inter-laboratory and international laboratory check sample programs had not been established.

Comments:

The Central Veterinary Microbiology Laboratory was conducting *E. coli* and *Salmonella sp* testing on product for potential export to the United States and for Dominican Republic's domestic microbiology sampling program.

This laboratory was using approved AOAC methods but was not ISO 17025 accredited.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agropecuaria Santo Domingo Km. 8, Carretera Villa Mella, La Victoria Santo Domingo, Dominican Republic	2. AUDIT DATE Sept 19, 2003	3. ESTABLISHMENT NO. 0006	4. NAME OF COUNTRY Dominican Republic	Page 1
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT		

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling		Audit Results
7. Written SSOP			33. Scheduled Sample		
8. Records documenting implementation.			34. Species Testing		X
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue		
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E - Other Requirements</b>		
10. Implementation of SSOP's, including monitoring of implementation.	X		36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import		
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.	X		39. Establishment Construction/Maintenance		X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			40. Light		
14. Developed and implemented a written HACCP plan.			41. Ventilation		X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories		
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			45. Equipment and Utensils		
18. Monitoring of HACCP plan.	X		46. Sanitary Operations		X
19. Verification and validation of HACCP plan.	X		47. Employee Hygiene		
20. Corrective action written in HACCP plan.	X		48. Condemned Product Control		X
21. Reassessed adequacy of the HACCP plan.	X		<b>Part F - Inspection Requirements</b>		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X		49. Government Staffing		
<b>Part C - Economic / Wholesomeness</b>			50. Daily Inspection Coverage		
23. Labeling - Product Standards			51. Enforcement		X
24. Labeling - Net Weights			52. Humane Handling		
25. General Labeling			53. Animal Identification		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pack Skins/Moisture)			54. Ante Mortem Inspection		
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection		
27. Written Procedures	X		<b>Part G - Other Regulatory Oversight Requirements</b>		
28. Sample Collection/Analysis	X		56. European Community Directives		O
29. Records	X		57. Monthly Review		
<b>Salmonella Performance Standards - Basic Requirements</b>			58. Animal Disease Controls		X
30. Corrective Actions			59.		
31. Reassessment					
32. Written Assurance					

## 60. Observation of the Establishment

Dominican Republic, Est. 0006, September 19, 2003 Est. Audit Form # 1.

Page 1

- 10/51) 1. The splitting saw drainage hose would contact the floor and then periodically touch the neck of carcasses.  
2. The work platforms for employees skinning legs and securing the bungs were constructed with an open grating which does not protect the end of the front shanks from drainage from the platform.  
3. Condensation was dripping onto carcasses between the organic acid spray area and the entrance into carcass cooler number one. Corrective actions were not initiated by establishment employees or by Dominican Republic inspection personnel.  
4. The dropped meat procedure written in the SSOP does not accurately describe the dropped meat procedure currently used to recondition meat.
- 13/51) 1. Preventive measures for pre-operational and operational sanitation were not documented in the daily pre-operational and operational sanitation records.  
2. Records for documenting the testing of back-flow devices were not available.
- 18/51) 1. Fecal material was identified on the ventral posterior midline of two consecutive carcasses checked by the FSIS auditor at the pre-boning contamination trim stand. The first carcass had three areas (one inch by three inches) of identifiable fecal contamination and the second carcass had one area (one half inch by three inches) of identifiable fecal contamination. A designated establishment employee was trimming the fecal contamination but corrective actions were not initiated by the establishment or by the Dominican Republic inspection officials.  
2. The number of boxes and carcasses to be monitored for respective critical control points were not stated in the HACCP plan.
- 19/51) 1. Initial validation documentation was missing from the HACCP plan.  
2. Validation documentation was missing from the HACCP plan for establishing critical limits.  
3. The same establishment employee was performing monitoring activities and verification of monitoring records for most critical control points.  
4. The frequency for some verification activities was not recorded in the HACCP plan.  
5. Verification activities did not include on-site observations or performance of the monitoring activity.
- 20/51) Preventive measures for corrective actions for a deviation from a critical limit was not included in the HACCP plan.
- 21/51) 1. The HACCP plan was not reassessed annually as required.  
2. The HACCP plan was not reassessed for *E. coli* O157:H7 as required.
- 22/51) Preventative measures for corrective actions for a deviation from a critical limit was not recorded in the records.
- 27/51) 1. The establishment did not have a written procedure for testing for generic *E. coli*.  
2. The carcass selection method was not random.
- 28/51) 1. The sample collector was not using aseptic collection techniques.  
2. The sample collector was using a 50 square centimeter template in lieu of the required 100 square centimeter template.
- 29/51) Statistical process control procedures had not been developed, as required, to evaluate the results of testing for generic *E. coli*. Results were not recorded on a process control chart.
- 34/51) Species testing is not currently conducted.
- 39/51) 1. Exposed insulation was identified in two areas of carcass cooler number one and carcass cooler number two.  
2. Peeling paint was identified in the over head support structures of carcass cooler number two.  
3. Carcass rails in carcass cooler number three were rusty.  
4. The ceiling and walls of box product cooler number two were constructed with rough porous concrete.  
5. Peeling paint was identified on the walls of the tripe room and the walls and ceilings of the first and second offal coolers.

Deficiencies one through five were identified during pre-operational sanitation.

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

W. Don Carlson 09/19/03

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agropecuaria Santo Domingo Km. 8, Carretera Villa Mella, La Victoria Santo Domingo, Dominican Republic	2. AUDIT DATE Sept 19, 2003	3. ESTABLISHMENT NO. 0006	4. NAME OF COUNTRY Dominican Republic	Page 2
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT		

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling		Audit Results
7. Written SSOP			33. Scheduled Sample		
8. Records documenting implementation.			34. Species Testing		X
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue		
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E - Other Requirements</b>		
10. Implementation of SSOP's, including monitoring of implementation.		X	36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import		
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.		X	39. Establishment Construction/Maintenance		X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			40. Light		
14. Developed and implemented a written HACCP plan.			41. Ventilation		X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories		
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			45. Equipment and Utensils		
18. Monitoring of HACCP plan.		X	46. Sanitary Operations		X
19. Verification and validation of HACCP plan.		X	47. Employee Hygiene		
20. Corrective action written in HACCP plan.		X	48. Condemned Product Control		X
21. Reassessed adequacy of the HACCP plan.		X	<b>Part F - Inspection Requirements</b>		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		X	49. Government Staffing		
<b>Part C - Economic / Wholesomeness</b>			50. Daily Inspection Coverage		
23. Labeling - Product Standards			51. Enforcement		X
24. Labeling - Net Weights			52. Humane Handling		
25. General Labeling			53. Animal Identification		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection		
<b>Part D - Sampling Generic <i>E. coli</i> Testing</b>			55. Post Mortem Inspection		
27. Written Procedures		X	<b>Part G - Other Regulatory Oversight Requirements</b>		
28. Sample Collection/Analysis		X	56. European Community Directives		O
29. Records		X	57. Monthly Review		
<b>Salmonella Performance Standards - Basic Requirements</b>			58. Animal Disease Controls		X
30. Corrective Actions			59.		
31. Reassessment					
32. Written Assurance					



## 60. Observation of the Establishment

Dominican Republic. Est.0006. September 19, 2003. Est. Audit Form # 2.

Page 2

- 41/51) 1. Condensation was identified in the over head of carcass cooler number one. The condensation was not over product, but carcasses must pass under the condensation to move out of the cooler.
2. Condensation was identified in the over head structures, over product, in carcass cooler number two.
3. Condensation was identified in the processing room. The condensation was located under two refrigeration units over the boning table.
4. Frozen condensation was identified under the refrigeration unit in box product cooler number two. No product was involved.
5. Condensation was identified under refrigeration units in the first and second offal coolers. No product was involved. Deficiencies one through five were identified during pre-operational sanitation.
6. Dripping condensation was identified in two areas of the boning room. Employees and exposed product moved through the area of dripping condensation. The same areas of condensation were identified during pre-operational sanitation. Corrective actions were not initiated by the establishment or by Dominican Republic inspection personnel.
7. Condensation was identified, over product in carcass cooler number one. Condensation was also identified in this area during pre-operational sanitation. Corrective actions were not initiated by establishment employees or Dominican Republic inspection personnel.
- 46/51) 1. Work clothes for establishment employees and government inspectors were washed inside but hung outside to dry. The area used to dry the clothes was located within 100 feet of the cattle pens and flies were observed on the work clothes.
2. Water was beading from a crack on the ceiling in the room used to clean trolleys and equipment for edible product.
3. Unidentified black specks were observed on the ceiling of the head boning room. A light cover containing numerous dead flies was identified in the same room.
4. Two inedible bone carts located in the boning room were scuffed and stained with unidentified back material. The two carts were not labeled as inedible.
5. The handle of a hand saw located in the dry landing area of slaughter room was stained and covered with old product residue.
6. The stainless steel framework of the window for the viscera lift located in the slaughter room, contained old product residue and ingesta smears.
7. The saw blade for the brisket saw was rusty.
8. Two rusty weld lines were identified in the lower compartment of a viscera inspection cart.
9. Paint was identified on product equipment and product tables in the viscera separation and tripe room.
10. A stainless steel table in the viscera separation room was covered with tripe chemicals from the previous days' operations.
11. Two blue plastic barrels used to transport edible tripe were severely scuffed. A two inch by three inch hole was identified in the bottom of one of the barrels.
- Deficiencies one through eleven were identified during pre-operational sanitation.
- 48/51) Dead and condemned cattle are brought into the slaughter establishment after normal production hours to prepare the dead animals for on-site rendering.
- 51) 1. The sample collector for the collection of *Salmonella* Performance Standards set samples was not using aseptic collection techniques.
2. The carcass selection method for collection of *Salmonella* samples was not random.
3. The sample collector for collection of *Salmonella* samples was using a 50 square centimeter template in lieu of the required 100 square centimeter template.
4. The sample results for *Salmonella* samples were not recorded as sample sets.
5. HACCP verification activities were not documented.
6. Operational sanitation verification activities were not documented.
- 58) Meat and bone meal rendered and prepared at this establishment is fed to cattle owned by this establishment or sold to other livestock producers. The meat and bone meal was not labeled.

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

 09/19/03

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Profile

Part A - General Information

1. ESTABLISHMENT NAME AND LOCATION

Agropecuaria Santo Domingo  
Km. 8, Carretera Villa Mella, La Victoria  
Santo Domingo, Dominican Republic

2. DATE

September 19, 2003

3. ESTABLISHMENT NO.

0006

4. NAME OF COUNTRY

Dominican Republic

Part B - Establishment Operation

5. TYPE OF OPERATION (check all that apply)



SLAUGHTER



FREEZER/COLD STORE



PROCESSING

6. SIZE OF ESTABLISHMENT (per HACCP criteria)



LARGE



VERY SMALL



SMALL

7. NUMBER OF ESTABLISHMENT  
EMPLOYEES

92

Part C - Processes/Products

8. SLAUGHTER



YOUNG  
CHICKENS



PORCINE



OVINE



CAPRINE



DUCKS



GEESE



GUINEA



MATURE  
CHICKENS



EQUINE



CALVES



TURKEYS



BOVINE



RATITES



OTHER

9. OTHER PRODUCT CATEGORIES



RAW MEAT (GROUND)



RAW MEAT (NOT GROUND)



THERMALLY PROCESSED/COMMERCIALY STERILE



NOT HEAT-TREATED (SHELF STABLE)



HEAT-TREATED (SHELF STABLE)



PRODUCT WITH SECONDARY INHIBITORS  
(NOT SHELF STABLE)



FULLY COOKED (NOT SHELF STABLE)



EGG PRODUCT



HEAT-TREATED  
(NOT FULLY COOKED/NOT SHELF STABLE)

10. SOURCE OF MEAT, POULTRY OR EGG PRODUCTS

SPECIES

COUNTRY OF ORIGIN

ESTABLISHMENT NUMBER

Bovine

Dominican Republic

Part D - Remarks (Use additional sheets of paper if necessary)

11. NAME OF AUDITOR

Dr. Don Carlson

12. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson - 09/19/03

Courtesy translation of the letter to Sally Stratmoen, Acting Director, Equivalence Division, Office of International Affairs, from W. Kasse Acta, Chief Meat Inspector for the Dominican Government, dated February 17, 2004

Dominican Republic  
*Secretariat of State for Public Health and Social Assistance*  
**“Social Security Year”**  
GENERAL DIRECTORATE OF ENVIRONMENTAL HEALTH

February 17, 2004

Ms. Sally Statmoen, Director  
International Equivalence Staff  
Office of International Affairs.

Dear Ms. Stratmoen:

In reply to your communication of 12-01-2003, related to the results of the AUDIT performed by Dr. Don Carlson from the 16<sup>th</sup> to the 25<sup>th</sup> of September on the Meat Inspection System in this Country in which you point up a series of sanitary deficiencies in different areas, I am pleased to comment on the information contained in the Final Draft of said audit according to the sections where said deficiencies appear.

## **6.1 Governmental Supervision**

- At present a committee was formed made up of the Pan American Health Organization (PHO), the Secretariat of State for Agriculture, and the Secretariat of State for Public Health, to prepare a national program for the monitoring, inspection, and contingency of Bovine Spongiform Encephalopathy (EEB), based on the Guidelines for Inspection of Neurological Syndromes in cattle, which was prepared by the PANAFTOSA/OPS/OMS/FAO Center.

### **6.1.4 Authority and responsibility in the application of the Law**

- A form (card) was prepared and put into execution to document the operational sanitary activities and the verification activities of the HACCP under the charge of the Official Veterinarian for Inspection in the establishment.

## **8. Laboratory Audit of Residues and Microbiology.**

Regarding the Microbiology Laboratory, a communication was sent to the director of the Central Veterinary Laboratory on 27-10-03, notifying him to proceed to perform the following as soon as possible:

- The checking of Inter-laboratory samples
- Checking of International samples

## **9.1 SSOP**

- An annual revalidation was made of the SSOP program which had been carried out in the audited establishment, and it is being monitored so that the establishment effectively implement the SSOP, implement the document of the records, and so that there is effective maintenance of same in order to complete the corrective actions and avoid their being misplaced.

The Official Inspection must monitor compliance with these actions.

## **9.2 Sanitation**

The Management of the audited establishment was sent a copy of the final report with the attached report forms (Checklists, form #1 and #2) so that it proceed to correct all of the deficiencies found:

- Construction and control of effective maintenance.
- Correct the condensation identified in the areas of products (refrigerators, de-boning rooms, and freezers).
- Improve the operational sanitation controls in order for them to be more effective.

## **10. Control of sick animals.**

- The Veterinarian in charge of the inspection of the establishment was instructed to apply strictly a control of condemned products, channels, parts of channels, and other rejected products, as provided by regulation No. 2430 on Sanitary Inspection of Meat and Meat Products for Export in its Title VII on Control and Destination of Rejected Inedible Materials Article No. 125, Letter A, B, and C and Number 1 and 2.
- The channels of cattle rejected in the ante-mortem inspection should not pass through areas of edible products, Article 128.
- Dead animals that arrive in the establishment should not enter the locale of same, and should be given the treatment provided by Article 129 on channels of dead animals Letter A and B which orders their immediate remitting to Rendering.
- The Secretariat of State for Agriculture and the Secretariat of State of Public Health are preparing a resolution which will regulate the manufacturing, distribution, and use of by-products of animal origin used in animal feed. This resolution will be applied in all establishments which produce bone dust and bone meal, prohibiting their use in ruminants, especially in bovine cattle. These by-products must bear a label indicating clearly the use which will be given to them and a daily control will be kept of the cooking temperature of the raw material.

- All factories which prepare balanced feed for cattle will be monitored periodically, and their products will be analyzed to determine whether they comply with this provision. The Veterinarians who have official inspectors in charge of Inspection in the establishments which perform Rendering will be responsible for the control and application of this measure.

## **11.2 Implementation of HACCP**

The establishment proceeded to perform an annual revalidation of the HACCP program. The establishment has been told to correct and proceed to perform the following:

- Proper monitoring of the HACCP according to the FSIS requirements.
- That the verification and validation be correctly and properly documented.
- That the corrective actions written in the HACCP plan be the proper ones.
- They proceeded to reevaluate the HACCP plan and control was included for E.coli 0157:H7.
- Records are being documented and complimented.

## **11.3 Test for generic E. coli**

The establishment has made a written revision of the methods for gathering samples for tests of generic E. coli which include the following:

- The method for selection of the channels is performed at random by means of a Random Numbering system on a calculation sheet identified as Random 1.xls, establishing the number of the refrigerator, the number of the line, and the number of the channel on the line.
- The person who takes the samples is using aseptic techniques of collection following the respective written guidelines.
- The person taking the sample is using a 100 cm. square card.
- A written control is being kept of the statistical processes in order to evaluate the results of E.coli to which the name of the A-14 registration sheet is given.
- The laboratory results of the samples for detection of E. coli are being statistically recorded on a control graph.

The written guide for the collection of E. coli was incorporated into the SSOP program.

## **12. Control of residues**

- It was communicated to the Central Veterinary Laboratory on October 23, 2003, that the Laboratory for the control of biological residues must implement the tests for Levamisole, Ivermectin, Benzimidazole, and Arsenic, as well as the checkings of Inter-laboratory samples the checking of International samples.

### **13.2 Test for Salmonella**

A written guide was developed following the instructions of FSIS for the gathering of samples and procedures for the isolation and identification of Salmonella from fresh meats, which has been incorporated into the HACCP program. This guide includes:

- The use of aseptic techniques for gathering of samples to detect Salmonella.
- The method of selection of channels is done at random through a Random Number sample on a calculation sheet identified as Random 2.slx, establishing the number of the refrigerator, the number of the line, and the number of the channel in the line.
- A 100 cm square card for the taking of samples.
- The results of the Salmonella samples are being recorded in a sampling set.

### **13.3. Verification of species.**

- This test is not being performed in view of the fact that the country is not authorized to export meat to the United States.

### **13.5 Inspection system Controls**

- The inspection system is putting emphasis on compliance with the regulatory requirements of FSIS. The Inspection Officials have been notified so that the individual reports of the establishment be identified upon verifying the activities of the SOOP and the HACCP in order that they may be corrected by the establishment.

On another note, I would like to point out that when all of the sanitary deficiencies indicated in the final audit report have been corrected, the FSIS will be notified so that the suspension for exporting meat to the United States be lifted.

If possible, I would appreciate a response to the comments made in the present communication, which would be of great assistance for the obtaining of the expected objectives.

Yours very truly,

Dr. Francisco W. Kasse Acta  
Chargé of Meat Inspection Service

Cc: Lic. Bruno Cedeño Nolasco – Director General of Environmental Health.  
Dr. Marcelino Vargas – Director General of Cattle Division  
Dr. Reynaldo Peña – Director of Animal Health